

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Georg **BERGER**, Andrea **SPITZER**, Christian **JAEGER**,
Jutta **PAULI** and Renate **GILDENHAAR**

Application No.: 10/689,217

Filed: October 20, 2003

For: **BONE REPLACEMENT MATERIAL WITH ORTHOPHOSPHATE**

Attorney Docket No.: 3975.023

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97 and §1.98

Mail Stop _____

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 56, Applicants hereby notify the U.S. Patent and Trademark Office of the following documents for the above-identified application which were cited in the specification of the present invention and/or by the Examiner in the corresponding German application. Copies of the documents set forth below and listed on the attached Form PTO-1449, are provided herewith.

1. European Patent Application No. 0 541 546 B1
2. European Patent Application No. 0 237 043 B1
3. German Patent Application No. DE 197 44 809 C1
4. World Patent Application No. 91/07357
5. U.S. Patent Application No. 6,117,456

Discussion of relevancy of references

Document 1

Document 1 is discussed in the present specification, and teaches a vitreous or vitreous-crystalline, rapidly dissolving material has the following composition (wt.%) before combustion: 20 - 55 CaO, 5 - 25 Na₂O, 0.01 - 15 K₂O, 0 - 15 MgO, 30 - 50 P₂O₅, 0 - 15 SiO₂, 0 - 40 Na₂SO₄ and/or K₂SO₄. The new material can be obtained in vitreous or vitreous-crystalline form, depending on the cooling conditions. As a spontaneously crystallized glass ceramic, it contains the rhenanite phase, 'A' phase, 'X' phase and/or their mixed crystals. The material is both bioactive and biocompatible and dissolves rapidly. It can be used directly and with other materials as an implant for temporary bone replacement and to induce growth of connective tissue, and as a fertilizer and fodder material. The claims of Document 1 are translated into English.

Applicants are not aware of any English language document in the patent family of Document 1, other than Document 4 which is in the family and contains an English language abstract.

Document 2

Document 2 concerns a sheet material which contains calcium phosphate and which is compatible with a biological medium. It consists of a main body which contains, as main constituent, calcium orthophosphate and on which there is situated at least one outer sheet releasing calcium ions, the release of calcium from the sheet being greater than the release of calcium from

the main body. The sheet material, which can be used as a temporary or permanent bone replacement substance, is produced by treatment with an acid or application of a sheet containing calcium compounds and subsequent heating between 400 and 1000°C.

The claims of Document 2 are translated into English. Applicants are otherwise not aware of any English language document corresponding to Document 2.

Document 3

Document 3 is entitled "Porous glass ceramic based on calcium phosphate useful as a bone substitute, drug, protein or cell substrate or filter aid" and concerns a porous, rapidly soluble, glass ceramic, comprising $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$, $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$ or $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$ as the main crystal phase. A porous, rapidly soluble, glass ceramic containing $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$, $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$ or $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$ as the main crystal phase has the following characteristics: (a) a boron content of 0.05-2 wt.%; (b) open pores with 33-80% overall porosity; (c) a pore diameter of 0.2-50 μm ; (d) a solubility of 300-4000 mg/l/day under simulated physiological conditions in 0.2M Tris-HCl buffer at 37 deg C and pH 7.1-7.5; (e) a chemical stability at a pH above 8; and (f) a surface area (BET) of 1-40 m^2/g . An Independent claim is also included for the preparation of the glass ceramic.

Document 4

A vitreous or vitreous-crystalline, rapidly dissolving material has the following composition (wt.%) before combustion: 20 - 55 CaO, 5 - 25 Na₂O, 0.01 - 15 K₂O, 0 - 15 MgO, 30 - 50

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P2O5, 0 - 15 SiO2, 0 - 40 Na2SO4 and/or K2SO4. The new material can be obtained in vitreous or vitreous-crystalline form, depending on the cooling conditions. As a spontaneously crystallized glass ceramic, it contains the rhenanite phase, ''A'' phase, ''X'' phase and/or their mixed crystals. The material is both bioactive and biocompatible and dissolves rapidly. It can be used directly and with other materials as an implant for temporary bone replacement and to induce growth of connective tissue, and as a fertilizer and fodder material.

Document 1 is a member of the family of Document 4, in which claims can be found which have been translated into the English language.

Document 5

Document 8 is submitted as an English language equivalent to Document 5.

The present Information Disclosure Statement is being filed after three months from the application's filing date but before the mailing date of the first Office Action on the merits, therefore no Certification Under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedated or otherwise remove any listed document as a

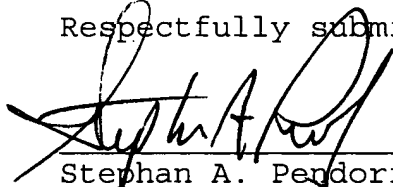
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competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,


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Reg. No. 32, 665

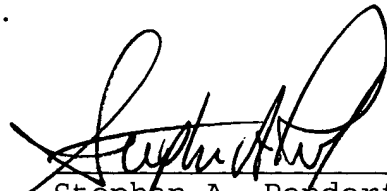
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Dated: **March 15, 2004**

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing INFORMATION DISCLOSURE STATEMENT Form PTO-1449, including five (5) documents, for U.S. Application No. 10/689,217 filed October 20, 2003, were deposited in first class U.S. mail, postage prepaid, P.O. Box 1450, Alexandria, VA 22313-1450, on **March 15, 2004**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application, except for the issue fee, without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.


Stephan A. Pendorf

